[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-

7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel Therapeutic Vector for Hemoglobin Disorders

Description of Technology: Investigators at the National Heart, Lung, and Blood Institute have designed a novel lentiviral vector as a potential gene therapy for sickle cell anemia and beta-thalassemia. The novel lentiviral vector encodes the beta-globin gene in a forward orientation and can produce 5-10 fold higher viral titer and 4-10 fold higher gene transfer efficiency to hematopoietic stem cells than reverse-oriented lentiviral vectors. In vivo studies conducted in rhesus macaques show beta-globin production after transplantation with this novel lentiviral vector. This technology could provide an alternative therapy for patients suffering from blood disorders associated with beta-globin gene mutations.

Potential Commercial Applications: Gene therapy

Competitive Advantages:

- Increased viral titers
- Increased transduction efficiency
- Large scale vector production

Development Stage:

- Early-stage
- In vitro data available

• In vivo data available (animal)

Inventors: Naoya Uchida and John F. Tisdale (NHLBI)

Intellectual Property: HHS Reference No. E-165-2014/0 - US Provisional Application No. 62/048,881 filed September 11, 2014

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D.; 301-495-4507; thalhamc@mail.nih.gov

Collaborative Research Opportunity: The National Heart, Lung and Blood

Institute is seeking statements of capability or interest from parties interested in

collaborative research to further develop, evaluate or commercialize this technology. For

collaboration opportunities, please contact Denise Crooks at crooksd@mail.nih.gov.

X-Clometer: Optimizing Portable Radiography

Description of Technology: The technology offered for licensing and commercial development relates to a method and apparatus that can significantly improve the diagnostic performance of portable chest (CXR) and abdominal x-rays. This device quantifies angulation of a patient to provide for a better comparison of day-to-day improvement.

The portable CXR is one of the most commonly requested diagnostic medical tests around the world. They are performed nearly daily on some of the sickest patients in hospitals. Paradoxically, it is well documented that portable radiography of the chest is inconsistent and often inadequate.

An upright projection best evaluates effusions, rules out free air, or detects airfluid levels. Optimally, the images are obtained at similar angles each day, even if not erect, to allow accurate comparisons and assessment of change. It is well documented that portable radiography of the chest is inconsistent and often inadequate. To achieve optimal quality of the exam the technologist attempts the most upright projection; balanced with patient condition and ability to achieve this often impossible task.

Potential Commercial Applications: Portable chest and abdominal x-rays performed at patient's hospital bedside.

Competitive Advantages:

- Currently, there is no quantitative marker to indicate degree of the upright position. Prior markers with small ball bearings sinking to a small circle only indicate if the patient is supine or not. This technology introduces a simple dynamic marker that can quantify the angle at a glance for the radiologist to best compare patient condition over time. This device objectively quantifies cassette angle with a ball bearing in a cylindrical tube with markers to indicate upright position in degrees.
- The technology improves performance of CXR, allowing reliable comparisons of patient condition over time. Thus, better therapies can be planned and unnecessary CT (Computerized Tomography) can be prevented.
- The technology improves care for Intensive Care Unit patients, as developing effusion and the need for immediate drainage (as one of many examples) can be more effectively assessed with the present apparatus. A widespread use of the device will save lives through improved diagnosis and comparison of effusions.

Development Stage:

• A performance of a visual prototype was demonstrated. The visual prototype was imaged at 5 selected angles with a chest phantom. Initial in-vitro results demonstrate that angles can be quantified to within 30 degrees.

• Improved prototypes with more accuracy are currently being manufactured for to patient use. In-vivo studies will soon be underway to validate clinical utility.

Inventors: Les R. Folio (CC) and Lucas S. Folio

Publications:

- 1. Wandtke JC. Bedside chest radiography. Radiology. 1994; 190:1-10. [PMID 8043058]
- 2. Pneumatikos I, Bouros D. Pleural effusions in critically ill patients.

 Respiration. 2008; 76(3):241-248. [PMID 18824883]
- 3. Mattison LE, et al. Pleural effusions in the medical ICU: prevalence, causes, and clinical implications. Chest. 1997 Apr;111(4):1018-1023. [PMID 9106583]
- 4. Fartoukh M, et al. Clinically documented pleural effusions in medical ICU patients: how useful is routine thoracentesis? Chest. 2002 Jan;121(1):178-184. [PMID 11796448]
- 5. Bekemeyer WB, et al. Efficacy of chest radiography in a respiratory intensive care unit. A prospective study. Chest. 1985 Nov; 88(5): 691-696. [PMID: 4053711]
- 6. Tocino I. Chest imaging in intensive care unit. Eur J Radiol 1996 Aug;23(1):46-57. [PMID 8872073]

Patent Status: HHS Reference No. E-036-2011/0 - US Patent Application No. 14/005,024 filed September 13, 2013

Licensing Contact: Tedd Fenn; 424-297-0336; tedd.fenn@nih.gov

6

Collaborative Research Opportunity: The NIH Clinical Center, Radiology and

Imaging Sciences, is seeking statements of capability or interest from parties interested in

collaborative research to further develop, evaluate, or commercialize X-Clometer. Please

contact Ken Rose, Ph.D. at 240-276-5509 or rosek@mail.nih.gov for more information.

Dated: May 14, 2015

Richard U. Rodriguez, M.B.A.

Acting Director

Office of Technology Transfer

National Institutes of Health

[FR Doc. 2015-12124 Filed: 5/19/2015 08:45 am; Publication Date: 5/20/2015]